



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SUBJECT: Product Chemistry Review of **Surfacine All-Purpose Cleaner**

DP Barcode: **D273265**
Manufacturing-use []

Reg. No. or File Symbol: **71661-R**
End-use Product [X]

Active Ingredient Composition:

Silver.....0.0095%

Poly(hexamethylenebiguanide)hydrochloride.....0.5600%

TO: Adam Heyward PM 34

FROM: Alex Traska, Chemist
Product Science Branch, CT Team
Antimicrobials Division (7510C)

AT 6/11/01

THRU: Karen P. Hicks, CT Team Leader
Product Science Branch
Antimicrobials Division (7510C)

KPH 6/11/01

THRU: Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510 C)

BACKGROUND:

This application for a new product registration, covering the subject disinfectant cleaner, was submitted by the Keller and Heckman LLP, agent's retained on behalf of the registrant, Intelligent Biocides, LLC.

The registrant, in this new product registration, has requested approval of an end-use product whose antimicrobial activity is based on the presence of silver

ions and poly(hexamethylenebiguanide) hydrochloride (PHMB). The unregistered source of silver ions come from the use of silver nitrate. The PHMB comes from two EPA registered sources which include [REDACTED]

[REDACTED] The registrant has followed the cite-all method of support for the two active ingredients in this registration.

The following documents were submitted and examined in the chemistry review of this submission: agent's cover letter and subsequent correspondence dated June 30, 2000 and February 28, 2001, registrant's "agency authorization letter" dated 2/6/01, agent's transmittal document February 9, 2001, application for new product registration dated February 7, 2001, Basic Formulation CSF with supplier addendum dated February 7, 2001, product label dated February, 2001 and Formulator's Exemption Statement, Certification with Respect to Citation of Data and Data Matrix all dated February 7, 2001. Also examined were the following documents: Product Chemistry Data for Guideline Series 830 dated February 9, 2001 and "primary" chemistry review for this submission which was made by the Oak Ridge National Laboratory. In this AD review, all relevant comments from the Oak Ridge "Data Evaluation Report", dated May 16, 2001, were incorporated into this "secondary" review.

FINDINGS:

1. The requirements of PR Notice 91-2 were satisfied. The nominal concentration of the active ingredients given in the Basic Formulation CSF agreed with the amount declared on the product label.
2. The certified upper and lower control limits for both the active and inert ingredients were acceptable.
3. All inert ingredients utilized in the formulation have been cleared for use in pesticide formulations.
4. The ingredient declaration on the label should show a "total" line and have the sum of the active ingredients and other ingredients totaling 100.0000%.

5. The ingredient declaration which was shown on the label should be revised to read as follows:

Active Ingredients:

Silver.....	0.0095%
Poly(hexamethylenebiguanide) hydrochloride.....	0.5600%
Other Ingredients:	<u>99.4305%</u>
Total	100.0000%

Note that the percentage of the " other ingredients" was increased to give a 100.0000% total.

6. The Product Chemistry Data for Guideline Series 830 were complete and consistent with the physical and chemical characteristic of this type of product. The following minor deficiencies noted in the primary review, in addition to those already mentioned, need to be addressed by the registrant:

a. in the case of the active ingredient, PHMB, the CSF should list the actual amount of the [REDACTED] PHMB solution utilized in the formulation and not just the nominal concentration of this active ingredient [REDACTED]

[REDACTED] The nominal concentration can be listed in the CSF directly below the actual amount of the [REDACTED] PHMB solution used.

b. no storage stability data was presented with this submission. Storage stability data , however, will be submitted to the Agency in ninety days. No corrosion characteristics study was specified, however, the product corrosion characteristics were identified as being non-corrosive to HDPE packaging.

7. All other elements of the CSF and Product Chemistry Data package were acceptable.

RECOMMENDATIONS:

This new product registration for the non-food hard surface disinfectant and cleaner, **Surfacine All-Purpose Cleaner**, is accepted with comment.

The registrant should address the minor deficiencies noted under Findings and provide the Storage Stability study on its completion.

06/01/01 AT

DATA EVALUATION RECORD

POLY(IMINOIMIDOCARBONYLIMINOIMIDOCARBONYLIMINOHEXAMETHYLENE) HYDROCHLORIDE AND SILVER (SURFACINE® ALL-PURPOSE CLEANER)

STUDY TYPES: Product Identity and Composition (OPPTS 830.1550)
Description of Beginning Materials (OPPTS 830.1600)
Description of Formulation Process (OPPTS 830.1650)
Discussion of Formation of Impurities (OPPTS 830.1670)
Preliminary Analysis, Certified Limits (OPPTS 830.1700, 830.1750)
Enforcement Analytical Method (OPPTS 830.1800)
Physical and Chemical Characteristics (OPPTS 830.6302 – 830.7950)
MRIDs 45328801, 45328802, and 45328803

Prepared for
Antimicrobials Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by
Chemical Hazard Evaluation Group
Toxicology and Risk Analysis Section
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37830
Work Assignment No. K281

Primary Reviewer:
Judith H. Moyer, Ph.D., D.A.B.T.

Signature: _____
Date: _____

Robert H. Ross
for Judith H. Moyer
MAY 16 2001

Secondary Reviewers:

Sylvia Milanez, Ph.D., D.A.B.T.

Signature: _____
Date: _____

Sylvia Milanez
MAY 16 2001

Robert H. Ross, M.S., Group Leader

Signature: _____
Date: _____

Robert H. Ross
MAY 16 2001

Quality Assurance:
Lee Ann Wilson, M.A.

Signature: _____
Date: _____

L. A. Wilson
MAY 16 2001

Disclaimer

This review may have been altered subsequent to the contractors' signatures above.

POLY(IMINOIMIDOCARBONYLIMINOIMIDOCARBONYLIMINO-
HEXAMETHYLENE) HYDROCHLORIDE, SILVER
MRIDs 45328801, 45328802, 45328803

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EPA Reviewer: Alex Traska, Ph.D. _____

Date: _____

EPA Work Assignment Manager: Bonaventure Akinlosotu, Ph.D. _____

Date: _____

Antimicrobials Division (7510C)

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Physical and Chemical Characteristics (OPPTS 830.6302-830.7950)

CASE NO.: 070100

P.C. CODE:

Ingredients	P.C. code	CAS No.
Active Ingredients		
Poly(hexamethylenebiguanide)hydrochloride	111801	32289-58-0
Silver (added as AgNO ₃)		
AgNO ₃	072503	7761-88-8
silver	072501	7440-22-4
Inert Ingredients		

DP BARCODE: D273265

SUBMISSION: S593644

MRID NOS.: 45328801, 45328802, 45328803

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Physical and Chemical Characteristics (OPPTS 830.6302 – 830.7950)

TEST MATERIAL: Surfacine® All-Purpose Cleaner (EPA Reg. No. 71661-R). The active ingredients are silver (added as silver nitrate: 0.0095% silver by weight, [REDACTED] and poly(hexamethylenebiguanide)hydrochloride (0.560% w/w).

SYNONYMS: poly(hexamethylenebiguanide)hydrochloride:
Poly(iminoimidocarbonyliminodocarbonyliminohexamethylene)hydrochloride; PHMB.HCL;
Revacil, Baquacil, Cosmoquil CQ; Vantocil

The silver was added as AgNO₃. Synonyms for AgNO₃: Lunar caustic; nitric acid [silver (+1) salt]

STUDY/REPORT NUMBERS: None provided

SPONSOR: Keller and Heckman LLP, 1001 G. Street, N.W., Suite 500 West,
Washington, D.C. 20001

TESTING FACILITIES: Intelligent Biocides, LLC, One Industrial Way, Tyngsboro, MA 01879

TITLE OF REPORTS: Application for Pesticide Registration: Surfacine® All-Purpose Cleaner, EPA File Symbol 71661-; Volumes 2 (MRID 45328801: Product Identity, Composition, and Production Process), 3 (MRID 45328802: Physical and Chemical Properties), and 4 (MRID 45328803: Enforcement Analytical Method)

AUTHORS: MRID 45328801: Yurkovetsky, A., Jovanovich, A.P., and Sawan, S.P.
MRID 45328802: Jovanovich, A.P., and Sawan, S.P.
MRID 45328803: Liu, F., Jovanovich, A.P., and Jardin, J.

REPORT ISSUED: February 9, 2001

EXECUTIVE SUMMARY: The product identity and composition, beginning materials, formulation process, potential impurities, certified limits, enforcement analytical method, and physical and chemical characteristics of the end-use product Surfacine® All-Purpose Cleaner (EPA Reg. No. 71661-R) were addressed in MRIDs 45328801, 45328802, and 45328803, the CSF and product label. Surfacine® is a ready-to-use, all-purpose spray cleaner and disinfectant for indoor hard surfaces with non-food applications in homes and hospitals. The product contains the active ingredients silver (0.0095% w/w, limits of 0.0086-0.0105% w/w; added as silver nitrate; no EPA Reg. No., but ingredient obtained from EPA-approved source) and poly(hexamethylenebiguanide)hydrochloride [PHMB.HCL, [REDACTED]

[REDACTED] The CSF does not state the amount of starting material of PHMB.HCL [REDACTED]

[REDACTED]. Surfacine® also contains inerts consisting of [REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] The certified limits given on the CSF were within guideline recommendations. The EUP is produced by a batch process, which is a mixing of EPA-approved active ingredients, and the inert ingredients. No impurities are formed during Surfaccine® formulation. Preliminary analysis was neither conducted nor needed since production was not by an integrated system. Spectrophotometric methods were used to determine the contents of the active ingredients in Surfaccine®. Physical and chemical characteristics were addressed adequately, with the exception of storage stability and corrosion, and the data required are noted in the "Classification of Studies" section below.

Classification of studies:

Product Identity and Composition (OPPTS 830.1550) – **Acceptable** but the CSF should be clarified by including the amount of the source material [REDACTED] added containing PHMB.HCL.

Description of Beginning Materials (OPPTS 830.1600) – **Acceptable**

Description of Formulation Process (OPPTS 830.1650) – **Acceptable**

Discussion of Formation of Impurities (OPPTS 830.1670) – **Acceptable**

Certified Limits (OPPTS 830.1750)- **Acceptable**

Enforcement Analytical Method (OPPTS 830.1800) – **Acceptable**

Physical and Chemical Characteristics (OPPTS 830.6302-830.7950) – Acceptable pending receipt of appropriate data for storage stability and corrosion characteristics (one-year study is required).

COMPLIANCE: Signed and dated Data Confidentiality statements were provided for MRIDs 45328801, 45328802, and 45328803. Signed and dated Quality Assurance statements were not provided. Each study report contained a signed statement that the "study does not meet the requirements of 40 CFR Part 160".

A. PRODUCT IDENTITY AND COMPOSITION (OPPTS 830.1550)

Surfaccine® All-Purpose Cleaner (EPA Reg. No. 71661-R) is an end-use product (EUP) that is a ready-to-use, all-purpose spray cleaner and disinfectant for indoor hard surfaces, with non-food applications in homes and hospitals. This product is a liquid blend, and contains the active ingredients silver [0.0095% w/w a.i., CAS No. 7440-22-4, source material is [REDACTED] solution of silver nitrate (AgNO₃), CAS No. 7761-88-8, no EPA Reg. No. but from an EPA-approved source] and

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poly(hexamethylenebiguanide)hydrochloride (PHMB.HCL) [0.560% w/w a.i., CAS No. 32289-58-0, source material is PHMB.HCL [REDACTED], although the amount of the source material is not specified on the CSF; [REDACTED]

The product contains the inerts [REDACTED]

[REDACTED] The submitted product label and the CSF are essentially in agreement, as the sum of inert ingredients is given as 99.43% w/w on the product label, and the inerts on the CSF total 99.4305% w/w. The suppliers of some of the actives and inerts were not listed on the CSF; rather, it was stated “see: CSF addendum”, but reviewer did not have this addendum.

B. DESCRIPTION OF BEGINNING MATERIALS, AND FORMULATION PROCESS
(OPPTS 830.1600, AND OPPTS 830.1650)

The beginning materials for Surfaccine® are the active ingredients silver (source material is a [REDACTED] solution of AgNO₃) and poly(hexamethylenebiguanide)hydrochloride or PHMB.HCL (source material is PHMB.HCL [REDACTED])

Surfaccine® is formulated [REDACTED]

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C. DISCUSSION OF FORMATION OF IMPURITIES (OPPTS 830.1670)

Surfacine® is manufactured by a simple mixing process. Because no chemical reaction occurs during the manufacturing process, the only impurities are those carried over from the starting materials. No migration from the packaging material was noted.

D. PRELIMINARY ANALYSIS (OPPTS 830.1700)

Preliminary analysis was not performed, and is not required because the EUP was formulated using registered active ingredients, and is not manufactured by an integrated system.

E. CERTIFIED LIMITS (OPPTS 830.1750)

The certified limits (lower – upper, percent by weight), provided on the CSF as % by weight of the product, were: 0.0086-0.0105% and 0.504-0.616% for the active ingredients silver and PHMB.HCL, respectively. Because [REDACTED] of PHMB.HCL was used in the formulation, the CSF should have also included the nominal and lower and upper limits for the actual amount of added source material for PHMB.HCL: [REDACTED]

[REDACTED]

[REDACTED] The upper and lower certified limits recommended by OPPTS 830.1750 guidelines were met by all chemicals. However, the number of significant figures used for certified limits were not rounded consistently, leading to a slight discrepancy for the sum of the inert ingredients provided on the product label (99.43% w/w) and the CSF (99.4305% w/w).

F. ENFORCEMENT ANALYTICAL METHOD (OPPTS 830.1800)

The methods used to determine the contents of the active ingredients of Surfacine®, silver and PHMB, were described. A silver sample was derivatized and analyzed using a Shimadzu AA-6200 atomic absorption spectrophotometer. The PHMB content in Surfacine® was analyzed using the dye eosin and a U.V. visible spectrophotometer with collimated optics.

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G. PHYSICAL AND CHEMICAL CHARACTERISTICS (OPPTS 830.6302-830.7950)

Color (830.6302): cloudy white with a yellow tint

Physical State (830.6303): liquid emulsion

Odor (830.6304): moderate Cellosolv-like odor

Melting Point (830.7200): not required by EPA for end-use products

Boiling Point (830.7220): not required by EPA for end-use products

Specific gravity (830.7300): 0.9976 g/ml at 24°C, determined using ASTM Method No. D 891-89, Method B

Solubility (830.7840): not required by EPA for end-use products

Vapor Pressure (830.7950): not required by EPA for end-use products.

Dissociation Constant (830.7370): not required by EPA for end-use products

Octanol/Water Coefficient (830.7570): not required by EPA for end-use products

pH (830.7000): 7.07 at 25°C using ASTM Method No. E 70-90 (CSF lists pH as 7.1 at 25°C)

Stability (830.6313): not required by EPA for end-use products

Oxidizing/reducing action (830.6314): no ingredients are oxidizing or reducing agents

Flammability (830.6315): not applicable; aqueous solution

Explodability (830.6316): determined nonexplosive on the basis of product's structure

Storage stability (830.6317): supplement with these data was to have been submitted. The stability test is referred to in the letter dated June 30, 2000, from Andrew P. Jovanovich (Keller and Heckman, LLC) to Marshall Swindell of the Antimicrobial Division OPP, EPA, but no storage stability test data were included in the applicant's packet.

Viscosity (830.7100): 1.80 centistokes (cSt) at 24°C using ASTM Methods No. D 445 and D 446

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Miscibility (830.6319): not required by EPA for this aqueous solution, as it is not intended to be diluted with petroleum solvents

Corrosion characteristics (830.6320): The report states “not corrosive to high density polyethylene packaging”, but the period over which this was tested was not specified (EPA guidelines require one year).

Dielectric breakdown voltage (830.6321): not required by EPA as the end-use product is not intended for use around electrical equipment

UV/Visible Absorption (830.7050): not required by EPA for end-use products

H. DISCUSSION

The product identity and composition, beginning materials, formulation process, formation of impurities, certified limits, enforcement analytical method, and physical and chemical characteristics for Surfacine® All-Purpose Cleaner (EPA Reg. No. 71661-R) were addressed in MRIDs 45328801, 45328802, and 45328803. The actives present in the EUP (w/w) are silver [REDACTED] and PHMB.HCL [REDACTED]. Inerts present in the EUP (w/w) are [REDACTED].

[REDACTED] No impurities were listed, but any present in the product would have been carried over from the starting materials and not created in the formulation process. The description of the formulation process was thorough. The silver content of the EUP was analyzed using a Shimadzu AA-6200 atomic absorption spectrophotometer, and the PHMB content in Surfacine® was analyzed using the dye eosin and a U.V. visible spectrophotometer with collimated optics. Storage stability (OPPTS 830.6317) data were not provided (although the study report indicated that the test results would be submitted as a supplement), and the length of time for the corrosion characteristics study was not specified.

Classification of studies:

Product Identity and Composition (OPPTS 830.1550) – **Acceptable** but the CSF should be clarified by including the amount of the source material [REDACTED] added containing PHMB.HCL.

Description of Beginning Materials (OPPTS 830.1600) – **Acceptable**

Description of Formulation Process (OPPTS 830.1650) – **Acceptable**

Discussion of Formation of Impurities (OPPTS 830.1670) – **Acceptable**

Certified Limits (OPPTS 830.1750) – **Acceptable**

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Enforcement Analytical Method (OPPTS 830.1800) – **Acceptable**

Physical and Chemical Characteristics (OPPTS 830.6302-830.7950) – Acceptable pending receipt of appropriate data for storage stability and corrosion characteristics (one-year study is required).

I. STUDY DEFICIENCIES

The CSF refers to an addendum but it was not provided to the reviewer.

The CSF should have listed the amount of the source material containing the a.i. PHMB.HCL, [REDACTED], instead of listing only the a.i. content [REDACTED]

[REDACTED] The product label and CSF are not in agreement for inert ingredients. The certified limits listed on the CSF were not rounded consistently, leading to a discrepancy for the sum of the inerts on the product label (99.43%) and the CSF (99.4305%).

No storage stability information was presented, and the period of time for the corrosion characteristics study was not specified.